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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,889	10/20/2000	Yair Feld	00/20989	7655

7590 07/29/2005

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ARLINGTON, VA 22202

EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/691,889	Applicant(s) FELD ET AL.	
	Examiner Anne-Marie Falk, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 24, 28-33, 35, 40, 42-46, 48-52 and 54-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24, 28-33, 35, 40, 42-46, 48-52 and 54-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The present application was filed containing a power of attorney to Sol Sheinbein, Martin Moynihan, D'vorah Graeser, and Rochel Abboudi. A correspondence address was supplied for Sol Sheinbein. No address was supplied for Martin Moynihan.

Sol Sheinbein was excluded from practice before the Patent and Trademark Office (Office). The Office does not communicate with attorneys or agents who have been suspended or excluded from practice.

As a correspondence address, other than to Sol Sheinbein, is not of record, this Office action is being mailed to the other practitioner of record at his/her last known address as listed on the register of patent attorneys and agents. To ensure that a copy of this Office action is received in a timely manner to allow for a timely reply, a copy of the Office action is being mailed directly to the address of the inventor first named in the declaration or oath. Any reply by applicant(s) should be by way of the remaining practitioner(s) of record and should include a new correspondence address.

The amendment filed May 2, 2005 has been entered. Claim 33 has been amended. Claims 34, 41, 47, and 53 have been cancelled.

Accordingly, Claims 23, 24, 28-33, 35, 40, 42-46, 48-52, and 54-60 are pending in the instant application.

The rejections of Claims 34, 41, 47, and 53 under 35 U.S.C. 112, first paragraph, for lack of enablement and lack of written description, are withdrawn in view of the cancellation of these claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57 and 58 are indefinite because they depend from cancelled Claim 34.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 24, 28-33, 35, 40, 42-46, 48-52, and 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2004/0266717 (Donahue et al., filed 9/6/00) and Koh et al. (1995).

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Donahue et al. discloses using a polynucleotide capable of modulating an electrical property in a standard cardiac electrophysiological assay and expressing the polynucleotide in the mammal to prevent or treat heart disease. The specification particularly discloses using polynucleotides that encode a K channel subunit, a Na channel subunit, and a Ca channel subunit.

Koh et al. (1995) disclose successful engraftment of fetal canine cardiomyocytes into the hearts of adult CXMD (canine X-linked muscular dystrophy) dogs. Confocal laser scanning microscopy revealed the presence of connexin43, the major constituent of the cardiac gap junction, at the donor-host cardiomyocyte border. Connexin43 immunoreactivity was apparent at junctional complexes between the donor and host cells (page 2038, column 2, paragraph 1).

Given that Donahue et al. disclose that it is desirable to deliver genes encoding ion channel proteins to cardiomyocytes for the treatment of cardiac arrhythmias and Koh et al. provides evidence that methods for engrafting cardiomyocytes are known in the art and that gap junctions form upon engraftment, the skilled artisan would have been motivated to transfect cardiomyocytes *ex vivo* using the polynucleotides as taught by Donahue et al. and then to implant the cardiomyocytes into the mammalian heart at appropriate locations as disclosed by Donahue et al. The skilled artisan would have had a reasonable expectation of success given the guidance of Koh et al. for engrafting and the guidance of Donahue et al. for treating cardiac arrhythmias using particular polynucleotides.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed.

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Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet.

The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

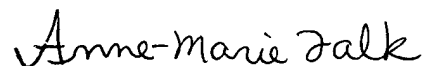
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.



ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER